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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/714,152 | 11/13/2003 | Sekhar Boddupalli | 29135-229 | 2364 |

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| EXAMINER | |
|---|---|
| QAZI, SABIHA NAIM | |
| ART UNIT | PAPER NUMBER |
| 1628 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/24/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/714,152 | BODDUPALLI ET AL. | |
| | Examiner | Art Unit | |
| | Sabiha Qazi | 1628 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2,6,7,11-13,18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 6, 7, 11-13, 18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Final Office Action**

Claims 2, 6, 7, 11-13, 18 and 20 are pending. No claim is allowed.

**Summary of this Office Action**

1. 35 USC § 112 (1) Written Description Rejection
2. Response to Remarks
3. Conclusion
4. Communication

**Claim Rejections - 35 USC § 112—Written Description Rejection**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 7, 11-13, 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply. Following reasons apply:

Claims are drawn to a method of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition comprising administering to an individual a composition comprising 3-(6-Hydroxy-2, 7, 8-

trimethyl chroman-2-yl)-propionic acid. Specification discloses an assay by which it was known that the compound reduces CRP level. There is no description how that of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition, comprising administering to the individual an effective amount of a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl- chroman-2-yl)-propionic acid, is related to reducing the level of an inflammatory marker in an individual subject to end-stage renal disease or the inflammatory marker is C-reactive protein (CRP) or ameliorating a symptom of an inflammatory condition, cardiovascular inflammatory condition, respiratory inflammatory condition, sepsis, diabetes, muscle fatigue, systemic lupus erythematosis (SLE), end stage renal disease (ESRD), premenstrual syndrome (PMS), and periodontal disease or when inflammatory marker is C-reactive protein (CRP) or IL-6.

Specification on page 19 discloses ELAM assay of three compounds which are different from comprising 3-(6-Hydroxy-2, 7, 8-trimethyl chroman-2-yl)-propionic acid. Further the methods of claims 6 and 11 find no possession at the time the invention was filed.

It appears that Applicant had no possession of the claimed subject matter at the time this application. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language.

See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "reducing the level of CRP and CRP **associated** condition, ameliorating a symptom of an inflammatory condition, cardiovascular inflammatory condition, CRP associated conditions" used herein), however, may not suffice to meet the written description requirement. This is

particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating: The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice…. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

The specification does not provide a reasonably representative disclosure of useful for reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition generally, a potentially huge genus

inclusive of many different compounds having widely divergent structures and functions.

Applicant is kindly requested to explain the issue. In the present case Applicant has no possession for the claimed subject matter. Further the compounds as in claim 1 covers large number of compounds to treat cancer. At the time invention was filed applicant has no possession of the invention as claimed.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas

that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). See MPEP 2163.06.

Applicant is kindly requested to explain.

**Response to Remarks**

Applicants' response filed on 8/31/10 is hereby acknowledged. Applicant's arguments were fully considered but are not found persuasive because specification does not disclosed the methods as presently claimed. The method of ameliorating a symptom of an inflammatory condition, cardiovascular inflammatory condition, CRP associated conditions and others as in claims 2, 6, 13 and 18 are not explained in the specification. Rejection is maintained for the reasons cited above.

In order to expedite the prosecution Applicant may consider calling the Examiner to discuss the issues related to this application.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612